REMARKS

Claims 1-3, 5, 10-11, 13-14, 17 and 19 were pending in the application.

Claims 1-3, 5, 10-11, 13-14, 17 and 19 remain pending in the application.

Claims Rejected under 35 U.S.C. §112

The Examiner has rejected claims 1-3, 5, 10-11, 13-14, 17 and 19 under 35 U.S.C. §112, first paragraph. The Examiner states that the Applicant does not provide sufficient data wherein at least one cortisol blocker and at least one anti-HIV drug are used together in a composition. The recipe for making this composition is fully laid out on pages 13-17 of the instant application. The weight ratios of anti-HIV drug to cortisol blocker are given (page 13, lines 12-14), the daily dosages in gms per kg of body weight are given (page 13, lines 14-20), the forms in which the drug can be administered are given (page 14, lines 1 and 2), the effective amount of the compounds is defined (page 14, lines 5-7), the single dosage and total daily dosage amounts are given (page 14, lines 7-9), the pharmaceutically acceptable inert ingredients are given (page 14, lines 10-22) and other materials that may be present in the composition are given (page 15, line 19 through page 16, line 4). In addition, on page 16, lines 3 and 4, the invention is defined as administering the anti-HIV drug and the cortisol blocker "separately to accomplish the objects of the present invention." Also, the invention is defined as either separate administration of the anti-HIV drug and the cortisol blocker or a composition defined as having both components systemically in the human body (see page 17, lines 1-4).

The Examiner's §112 rejections concerning the reduction of side effects are moot, as all claims to the reduction of side effects had been previously canceled.

Claims Rejected under 35 U.S.C. §103

The Examiner has rejected claims 1-3, 5, 10, 11, 13, 14, 17 and 19 under 35 U.S.C. §103. The Examiner has stated that the Applicant has claims drawn to a method for the management of side effects but all those claims have been changed or canceled. Claims 1 and 10 are the remaining independent claims. Claim 1 is to a composition and Claim 10 is to the method of treating HIV-infected patients.

The Applicant's attorney has prepared a Declaration under 37 C.F.R. §1.132 detailing a study performed at Georgetown University Medical Center in which the Applicant's drug therapy, which is the subject of the present patent application, has revealed a synergist effect and that there are unexpected results encountered during this study. The anti-cortisol effect of the combination of drugs, which are the subject of the present invention, was extremely elevated when compared with the anti-cortisol capabilities of each ingredient taken separately. The acceptance of the attached Declaration should lead to the proper withdrawal of the §103 rejections. The attached Declaration could not have been submitted at an earlier time because it was not brought to our attention until June 1, 2000 (since the study was not released until May 12, 2000).

Conclusion

With the clarification as to how the composition is made pointed to in the specification, with the prior cancellation of claims to the side effects, and with the attached Declaration in

support of patentablility the present application is now in condition for allowance and such action is earnestly requested. A telephone conference regarding this application is earnestly desired and encouraged.

Respectfully submitted,

Dated: 9/19/00

By: Cheryl S. Scotney

Cheryl S. Scotney, Reg. No. 46,218
Attorney for Applicants
Standley & Gilcrest LLP
495 Metro Place South, Suite 210
Dublin, Ohio 43017-5315
Telephone: (614) 792-5555
Facsimile: (614) 792-5536